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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
CHEN, STACY BROWN	
ART UNIT	**PAPER NUMBER**
1648	

DATE MAILED: 07/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/030,441	FAN ET AL.	
	Examiner	Art Unit	
	Stacy B Chen	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 May 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2 and 4-59* is/are pending in the application.

4a) Of the above claim(s) *13-36 and 42-59* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4-12 and 37-41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *07 January 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment filed May 26, 2004 is acknowledged and entered. Claims 1, 2, 4-12 and 37-41 are examined. Claims 13-36 and 42-59 have been withdrawn from consideration being drawn to non-elected inventions.

2. The following objections or rejections have been withdrawn:

- The objection to claim 37 has been withdrawn in view of Applicant's amendment.
- The rejection of claims 1-3 under 35 U.S.C. 102(b) as being anticipated by York *et al.* (*J. Virol.* 65:5061-5067), herein, "York", has been withdrawn or is moot in view of Applicant's amendment limiting claims 1 and 2 to SEQ ID NO: 8 and canceling claim 3, respectively.
- The rejection of claim 3 under 35 U.S.C. 112, first paragraph, is moot in view of its cancellation.
- The objection to the specification for failing to indicate the extent of public availability of the deposit AF105220 (Gen Bank) is moot because claim 3 has been cancelled.

(Note that while the amendment filed May 26, 2004 indicates that the deposit was made under the terms of the Budapest Treaty, the specification still fails to indicate the extent of public availability. If a deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made under the terms of the Budapest Treaty and that all restrictions imposed by the depositor on the availability to the public of the deposited material will be

irrevocably removed upon the granting of a patent, would satisfy the deposit requirements. See 37 CFR 1.808.)

Specification

3. The specification remains objected to because of one embedded hyperlink on page 27.

4. The amendment filed May 26, 2004 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: SEQ ID NO: 8. Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

5. (*New Rejection*) Claims 37-41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 37 recites "the immune response ameliorates the effect of an infection by a JSRV or related viral particle". It is unclear what is meant by "effect of an infection". What is an effect of an infection besides an infection? How does one measure that the effect has been ameliorated? What endpoints indicate that an improvement has taken place regarding the effect? Further, the specification fails to define "related" viral particles to JSRV. It is not clear what a related particle's characteristics are in terms of structure.

6. (*New Rejection*) Claims 1-2 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In the amendment filed May 26, 2004, Applicant introduced into the specification SEQ ID NO: 8, a polynucleotide of the JSRV sequence having accession number AF105220. SEQ ID NO: 8 was also introduced into claim 1 and dependent claim 2. SEQ ID NO: 8 was not present in the originally filed specification and is therefore new matter. Other sequences that were introduced by the amendment filed May 26, 2004 are not new matter because they were either in the figures 5, 6 and 8, or spelled out in the specification. However, there is no evidence that SEQ ID NO: 8 was present in the specification as originally filed.

7. The rejection of claims 37-41 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is maintained for reasons of record. The claims are drawn to a pharmaceutical composition comprising a JSRV or JSRV polypeptide that elicits an immune response that ameliorates the effect of an infection by a JSRV or related viral particle. Applicant's arguments have been carefully considered but fail to persuade. Applicant's substantive arguments are primarily directed to the assertion that Applicant had possession of a pharmaceutical composition that provides therapeutic benefit.

- Applicant points to the specification on page 62, lines 25-31, indicating that envelope proteins of JSRV "are particularly useful in sensitizing the immune system of an animal

such that, as one result, an immune response is produced which ameliorates the effect of an infection by a JSRV or related viral particle".

- In response, the specification fails to show possession of a pharmaceutical composition. The specification only shows possession of a JSRV protein that sensitizes the immune system. No amelioration of any effect of infection with JSRV is indicated.

- Applicant refers to Exhibit A in the response filed May 26, 2004, which discloses that sheep naturally infected with JSRV and develop lung cancer do not develop antibodies to the virus. Further, Applicant has found that animals inoculated with recombinatly expressed JSRV gag or envelope proteins raise antibodies to JSRV. Applicant then concludes that inducing an immune response provides therapeutic benefit of alleviating symptoms associated with infection.

  - In response, inducing an immune response to JSRV does not indicate that an effect of JSRV infection has been improved. Applicant has not shown possession of a JSRV or JSRV polypeptide that alleviates the symptoms of an infection.

8. The rejection of claims 37-41 under 35 U.S.C. 112, first paragraph, for containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to make and/or use the invention is maintained for reasons of record. The claims are drawn to a pharmaceutical composition comprising a JSRV or JSRV polypeptide that elicits an immune response that ameliorates the effect of an infection by a JSRV or related viral particle.

Applicant's arguments have been carefully considered bu fail to persuade. Applicant's substantive arguments are primarily directed to the assertion that there are treatments for JSRV.

- Applicant points to the specification on page 62, lines 25-31, indicating that envelope proteins of JSRV "are particularly useful in sensitizing the immune system of an animal such that, as one result, an immune response is produced which ameliorates the effect of an infection by a JSRV or related viral particle". Applicant asserts that a method of treating a JSRV infection is ameliorating the effect of the infection.
    - In response, the specification fails to show that a JSRV or JSRV polypeptide can provide a therapeutic benefit to an infected subject. The specification only shows that an envelope JSRV protein sensitizes the immune system. No amelioration of any effect or alleviation of symptoms associated with JSRV infection is supported by the specification.
- Applicant asserts that guidance for making and using a pharmaceutical composition providing therapeutic benefit can be found in the specification on page 62, lines 25-31. Applicant also argues that working examples are not required and that undue experimentation is determined by weighing many factual considerations.
    - In response, the Office recognizes that the lack of a working examples is not by itself a reasons for concluding that an invention would require undue experimentation. However, in the last Office action, the factual considerations were weighed and it was determined that because of the breadth of the claims, the state of the art, the level of one of ordinary skill, the level of predictability and the lack of working examples and guidance from the specification, the claims are not

enabled for their full scope. The guidance provided in the specification on page 62, lines 25-31 is not an enabling disclosure. Simply saying that the JSRV envelope protein sensitizes the immune system of an infection animal fails to teach one how to make a pharmaceutical composition that alleviates symptoms of JSRV infection. In summary, Applicant is enabled for an immunogenic composition.

Claim Rejections - 35 USC § 103

9. The rejection of claims 37-41 under 35 U.S.C. 103(a) as unpatentable over York in ivew of Salk *et al.* (6,017,543), herein "Salk", and Gilbert *et al.* (5,017,543), herein "Gilbert", is maintained for reasons of record. The claims are drawn to a pharmaceutical composition comprising a JSRV or JSRV polypeptide that elicits an immune response that ameliorates the effect of an infection by a JSRV or related viral particle. The composition contains an adjuvant. The JSRV is a non-infectious, heat-inactived virus. The JSRV polypeptide is an enveloped polypeptide. Applicant's arguments have been carefully considered but fail to persuade. Applicant's substantive arguments are primarily directed to the assertion that the Office has failed to provide objective evidence of any suggestion or motivation to combine and modify the references to arrive at the claimed invention.

- Applicant argues that York fails to teach SEQ ID NO: 8 comprising Long-Terminal Repeat (LTR) sequences at the 5' and 3' end of the retroviral genome, wherein the LTR is active in pulmonary epithelial cells. Applicant further argues that neither Salk nor Gilbert, nor the combined disclosures thereof, cure the deficiencies of York.

- In response, the limitations of SEQ ID NO: 8, LTR sequences and activity in pulmonary epithelial cells are not claimed in claims 37-41.

- Applicant argues that the new limitation of "wherein the immune response ameliorates the effect of an infection by a JSRV or related viral particle" has not been taught by Salk. Applicant asserts that there is no obvious indication that the use of heterologous genes in a viral vector will induce an immune response to ameliorate the effect of an infection by a JSRV.

  - In response, the claims are interpreted as immunogenic compositions only, having no therapeutic benefit. (See rejection of claims 37-41 under 35 U.S.C. 112, first paragraph, and Office Action of February 24, 2004, page 9, first paragraph.) Since the claims are not being interpreted as pharmaceutical compositions that ameliorate the effect of an infection by a JSRV, Applicant's argument does not apply in this instance.

- Applicant argues that there is no suggestion, and thus no expectation of success in combining the teachings of York with Salk and Gilbert to arrive at the claimed invention.

  - In response, with regard to immunogenic compositions, one would have been motivated to use JSRV in an immunogenic composition because Salk and Gilbert use retroviruses to elicit immune responses. (See Office Action, February 24, 2004, page 9).

10. The rejection of claims 4-12 under 35 U.S.C. 103(a) as unpatentable over Kasahara *et al.* (6,410,313), herein "Kasahara", in view of York, is maintained for reasons of record.

Applicant's arguments have been carefully considered but fail to persuade. Applicant's substantive arguments are primarily directed to the assertion that there is no obvious indication that the use of heterologous genes in a viral vector will induce an immune response to ameliorate the effect of an infection by a JSRV.

- Applicant argues that success with one retrovirus does not guarantee success with another. Applicant also argues that there is no suggestion, and thus no expectation of success in combining the teachings of York with Kasahara to arrive at the claimed invention.
    - In response, Applicant has not provided any objective evidence that JSRV would not work using the same model taught by Kasahara for an oncoretrovirus. One would have been motivated to use JSRV in Kasahara's model because Kasahara teaches that other retroviruses can be used that are replication competent and do not require helper virus or additional nucleic acid sequence or proteins in order to propagate and produce virions (Office Action, February 24, 2004, page 11). Since JSRV is linked with cancer, and Kasahara is using an oncoretrovirus, one would have had a reasonable expectation of success that the same model would have worked to produce a JSRV.

Conclusion

11. No claim is allowed. SEQ ID NO: 8 is free of the prior art of record.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stacy B. Chen whose telephone number is 571-272-0896. The examiner can normally be reached on M-F (7:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James C. Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Stacy B. Chen

June 30, 2004

James C. Housel 7/12/04

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